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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,777	01/12/2001	Maria Isabel Gonzalez	5771-P1-01-BD	9663

7590

01/15/2002

Warner-Lambert Company
2800 Plymouth Road
Ann Arbor, MI 48105

EXAMINER

BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
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1617

3

DATE MAILED: 01/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/759,777

Applicant(s)

GONZALEZ ET AL.

Examiner

Mojdeh Bahar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12, 14-16 recite the limitation "vasodilator" in line 1 of each claim. There is insufficient antecedent basis for this limitation in the claim. Claim 13 recites "PDE5 inhibitor" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Howell et al. (WO 98/07718).

Howell et al. (WO 98/07718) teaches a method of treating and o/or preventing depression employing a oral pharmaceutical composition/dosage form comprising non-peptide bombesin receptor antagonists, see particularly, abstract, page 10 and claims 11-12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howell et al. (WO 98/07718) and Hurel et al. in view of Merck Manual and sildenafil prescribing information.

Howell et al. (WO 98/07718) teaches a method of treating and/or preventing depression employing a oral pharmaceutical composition/dosage form comprising non-peptide bombesin receptor antagonists, see particularly, abstract, page 10 and claims 11-12.

Hurel et al. teaches that bombesin-like peptide antagonists have vasoactive properties, see page 1243.

Howell et al. (WO 98/07718) and Hurel et al. taken together do not particularly teach the employment of bombesin-like peptide and/or non-peptide antagonists in a method of treating sexual dysfunction. Neither do they teach the combination of vasodilators, neurotransmitter antagonists and/or agonists or a hormone like compound in its method of treating sexual dysfunction.

Merck Manual teaches depression, low testosterone level and vascular abnormalities as causes of sexual dysfunction, see pages 1575 and 1577-78.

Sildenafil is a known vasodilator employed in the treatment of sexual dysfunction, see pages 5-6.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ bombesin-like peptide and/or non-peptide antagonists in a method of

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treating sexual dysfunction. It would also have been obvious to combine the bombesin receptor antagonist with vasodilators, neurotransmitter antagonists and/or agonists or a hormone like compound in a method of treating sexual dysfunction.

One of ordinary skill in the art would have been motivated to employ bombesin-like peptide and/or non-peptide antagonists in a method of treating sexual dysfunction because (1) they are known to be employed in methods of treating depression which is known to be an underlying cause of sexual dysfunction; (2) they are known to be vasoactive which are known to be useful in treating sexual dysfunction. One of ordinary skill in the art would have also been motivated to combine the bombesin receptor antagonist with vasodilators, neurotransmitter antagonists and/or agonists or a hormone like compound in a method of treating sexual dysfunction since they are all known to be useful in treating sexual dysfunction. Combining agents that are known to be useful for the same purpose in a combination composition to be used for the same purpose is known to be within the skill of the artisan and therefore obvious, see *In re Kerkhoven* 205 USPQ 1069.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
January 14, 2002


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200